UNITED STATES PATENT APPLICATION

OF

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FOR

PACKAGING DEVICE AND METHOD

PACKAGING DEVICE AND METHOD

[0001] This invention claims the benefit of U.S. Provisional Patent Application No. 60/457,790, filed on March 26, 2003, which is hereby incorporated by reference.

BACKGROUND OF THE INVENTION

Field of the Invention

[0002] The present invention relates to a packaging device and method, and more particularly to a bio-hazardous equipment packaging device and method for safely and economically transporting bio-hazardous equipment through courier or mail services for cleaning, maintenance, disposal or other event. The invention is particularly adapted for the medical technologies, and can be used in the transport of used medical equipment.

Description of the Related Art

[0003] A common system for packaging and shipping used medical equipment/devices is to repackage the device in its original equipment packaging to ship it. Typically, new medical devices are provided with a suitcase that has a foam insert for securing the medical device in the

suitcase and for preventing it from moving and damaging itself. The suitcase is often a hardshell type suitcase with locks on one edge, similar to hardshell luggage.

[0004] Medical shipping personnel sometimes package a used medical device in its original case for shipment to a cleaning, repair or other facility after the medical device has been used. Sometimes the shipper will include a note to indicate that the medical device has not been disinfected. This procedure places many persons at risk of contamination during the shipping process, and also places patients of the medical device at risk of cross-contamination. Risk of contamination occurs when liquids from the used medical device seep out of the device and into the foam insert and, sometimes, out of the case itself. In order to remedy the problems associated with this type of contamination, the case and foam insert must be disinfected before the medical device is returned or shipped to another location. However, disinfecting the case and the foam insert is difficult, expensive and time consuming. Many times, the recipient of the used medical device does not take the step of disinfecting the case and foam insert.

[0005] Another way that used medical devices are often shipped is by placing a plastic bag or plastic liner over the foam insert in the original case, placing the used medical device onto

the plastic liner or bag, folding the liner or bag over the medical device (with or without sealing the bag or liner) and then closing the case over the medical device, and shipping it. Again, the case and foam insert can be easily contaminated when this shipping procedure is utilized. Liquid and biological materials can seep into or otherwise contaminate the foam and case. Disinfecting the foam insert and/or case after this shipping procedure is extremely inefficient and difficult, and many times it is not undertaken.

[0006] After-market die cut foam sets are also available for use in the shipment of used medical equipment/devices. In some cases, the used medical equipment is placed in the after market foam piece, which is then placed in a cardboard box (or sometimes the original case), and the box (or case) is shipped to the repair, disinfecting or other location. This procedure is more effective at preventing cross-contamination (if new foam inserts are used during shipping and return) and thus protecting future patients of the medical device, but the shipping procedure has the drawback that it places the shippers and handlers of the device at risk of contamination. There is no waterproof barrier to protect the many shippers and handlers of the device. In addition, the after-market foam pieces are very large and require a great deal of storage space. In

hospitals, storage space is a premium. Accordingly, this type of shipping procedure presents a major drawback to shippers of medical equipment located at hospitals and medical facilities. The space requirement of this type of shipping apparatus/ procedure is also inconvenient for the repair, cleaning other receiving facilities, as well as for the sales persons involved with any aspect of repair or cleaning of medical equipment/devices. In addition, disposal of the used foam inserts is costly and presents environmental problems since they typically end up taking a large amount of space in land fills.

[0007] In some instances, medical device shippers have used a cardboard box filled with conventional foam sheets, bubble wrap, or "peanuts" to secure the medical device in the cardboard box and protect it from movement and jarring. This method has many of the same drawbacks as outlined above regarding the other conventional methods and apparatus for shipping used medical devices/equipment. Namely, risk of contamination is high and the remedy for contamination is cost prohibitive and detrimental to the environment.

[0008] The present invention has been made in consideration of the above and other problems, remedies, and conveniences.

SUMMARY OF THE INVENTION

In accordance with an aspect of the present invention, an endoscope equipment shipping device, can include an inflatable bladder that is configured to fit within a standard case supplied with new endoscope equipment when foam inserts are removed from the standard case; a plurality of baffles located at predetermined locations in the bladder such that when the bladder is inflated, the shipping device takes the form of the standard case's interior volume when the foam inserts are removed from the standard case; and a valve located adjacent the inflatable bladder.

In accordance with another aspect of the invention, the endoscope equipment can include an inflatable bladder shaped such that when the inflatable bladder is configured for shipping it forms a pouch with a front side, a rear side, and an open edge, the front side and rear side being configured to contain the endoscope equipment therebetween when the bladder is configured for shipping, and the open edge having a seal for closing the pouch. The baffles can include a plurality of horizontally oriented baffles and at least one vertically oriented baffle. The shipping device can have a maximum height and maximum width of approximately 18 inches by

approximately 2 feet, respectively, when in a totally inflated state. The shipping device can also have a maximum thickness of approximately 5 inches when in a totally inflated state. The bladder can be configured to form a pouch such that the shipping device has three closed edges, an open edge, and a front side and a rear side, and the bladder can include a plurality of horizontally oriented baffles in the front side of the pouch, and a plurality of horizontally oriented baffles in the rear side of the pouch. The bladder can include a baffle configured to frame the plurality of horizontally oriented baffles in the front side of the shipping device. The shipping device can have a maximum height and maximum width of approximately 18 inches by approximately 2 feet, respectively, when in an inflated state and configured for placement into the standard case supplied with a new endoscope when the foam inserts are removed from the standard case. The shipping device can also include a front side attached to a rear side by a hinge portion, and the shipping device can have a maximum height and maximum width of approximately 18 inches by approximately 2 feet when in the inflated state and configured for shipment, such that when the shipping device is configured for shipment, it fits into the standard case supplied with a new endoscope when the foam inserts are removed from the standard case.

[0009] In accordance with another aspect of the invention, an equipment shipping kit can include a pouch formed by at least one inflatable bladder and a plurality of baffles, and a valve located on the inflatable bladder. A protective structure configured to be placed over a portion of the equipment to protect the pouch during shipment of the equipment can also be provided.

[0010] In accordance with another aspect of the present invention, the kit can include a primary pouch including an open edge or open end having a resealable seal and a secondary pouch including an open end having a resealable seal. The secondary pouch can include an enclosure configured to store paperwork therein. The kit can also include a return pouch formed by at least one inflatable bladder and including a plurality of baffles, and a valve located on the inflatable bladder of the return pouch. Alternatively, the inflatable pouch can be formed with a top portion, a bottom portion, and a hinge connecting the top portion and bottom portion. An adherence portion can be located at one of the top portion and the bottom portion such that when the inflatable pouch is folded along the hinge, the top portion and bottom portion can be adhered to each other to form a containment area between the top portion and bottom portion. In another

alternative, the inflatable pouch can include a resealable opening located at an end of the inflatable pouch.

[0011] According to yet another aspect of the invention, an equipment shipping kit can include a pouch formed by at least one inflatable bladder that has a plurality of baffles and a valve located on the inflatable bladder, and a primary pouch including an open end having a resealable seal.

[0012] In accordance with another aspect of the invention, the equipment shipping kit can further include a secondary pouch including an open end having a resealable seal and a plurality of caps configured to be placed over portions of the equipment to protect the pouch during shipment of the equipment. A return pouch formed by at least one inflatable bladder can be provided, including a plurality of baffles, a resealable opening located at an end of the return pouch, and a valve located on the inflatable bladder of the return pouch. The inflatable pouch can include an inner layer made from polyethylene /nylon/polyethylene co-extrusion and an outer layer made from nylon/polyethylene laminate. The inflatable pouch can alternatively include a top portion, a bottom portion, and a hinge connecting the top portion and bottom

portion. An adherence portion can be located at one of the top portion and the bottom portion such that when the inflatable pouch is folded along the hinge, the top portion and bottom portion can be adhered to each other to form a containment area between the top portion and bottom portion. Furthermore, the inflatable pouch can include a resealable opening located at an end of the inflatable pouch.

[0013] According to another aspect of the invention, a method for shipping medical equipment can include providing an inflatable pouch formed by at least one inflatable bladder including a plurality of baffles, and a valve located on the inflatable bladder; providing a plurality of caps; placing the caps over portions of the medical equipment; placing the medical equipment onto the pouch; inflating the pouch via the valve; and shipping the medical equipment and pouch.

[0014] In accordance with another aspect of the invention, the method can include sealing the pouch via a resealable air tight seal. The method can also include providing a primary pouch and placing the medical equipment into the primary pouch prior to shipping. In addition, the method can include providing a secondary pouch, and placing the medical

equipment and primary pouch into the secondary pouch prior to shipping. The medical equipment provided can be an endoscope. In addition, the medical equipment that is shipped may not be disinfected prior to shipping. Alternatively, the method can include providing the inflatable pouch with a top portion, a bottom portion, and a hinge connecting the top portion and bottom portion. The step of placing medical equipment on the inflatable package can include folding the inflatable pouch along the hinge to form a containment space between the top portion and bottom portion. In addition, the method can include adhering the top portion to the bottom portion of the inflatable pouch to contain the medical equipment therein.

[0015] In accordance with another aspect of the invention, a method for shipping medical equipment can include providing an inflatable pouch formed by at least one inflatable bladder including a plurality of baffles, and a valve located on the inflatable bladder; providing a primary pouch; placing the medical equipment into the primary pouch; sealing the primary pouch; placing the primary pouch on the inflatable pouch; inflating the inflatable pouch via the valve; and shipping the medical equipment, primary pouch and inflatable pouch.

[0016] In accordance with another aspect of the invention, the method can include providing a secondary pouch; placing the primary pouch into the secondary pouch; placing the secondary pouch on the inflatable pouch; and shipping the secondary pouch with the medical equipment, primary pouch and inflatable pouch. The method can also include providing caps and placing the caps over portions of the medical equipment to protect the inflatable pouch from the medical equipment. The medical equipment can include an endoscope, and the method can include providing a case, and placing the inflatable pouch and medical equipment into the case prior to shipping. The case can be a cardboard box. The method can also include providing a second inflatable pouch, and shipping the second inflatable pouch with the first inflatable pouch and medical equipment. The inflatable pouch can include a top portion, a bottom portion, and a hinge connecting the top portion and bottom portion, and the method can include folding the inflatable pouch along the hinge to form a containment space between the top portion and bottom portion. The method can also include adhering the top portion to the bottom portion of the inflatable pouch to contain the medical equipment therein.

[0017] In accordance with yet another aspect of the invention, a method for shipping medical equipment can include providing an inflatable pouch formed by at least one inflatable bladder including a plurality of baffles, and a valve located on the inflatable bladder; providing a case, for example the case in which the original medical equipment was provided; placing the medical equipment onto the inflatable pouch; sealing the inflatable pouch; inflating the inflatable pouch via the valve; placing the inflatable pouch in the case; and shipping the medical equipment, inflatable pouch and case.

[0018] In another aspect of the invention, the method can include providing a primary pouch; placing the medical equipment into the primary pouch; placing the primary pouch on the inflatable pouch; and shipping the primary pouch with the medical equipment, inflatable pouch and case. The method can also include providing caps; and placing the caps over portions of the medical equipment to protect the inflatable pouch from the medical equipment. The medical equipment can include an endoscope, and the case can be a cardboard box. The method can also include providing a second inflatable pouch, and shipping the second inflatable pouch with the first inflatable pouch and medical equipment. The inflatable pouch can include a top portion, a

bottom portion, and a hinge connecting the top portion and bottom portion, and the method can include folding the inflatable pouch along the hinge to form a containment space between the top portion and bottom portion. The method can further include adhering the top portion to the bottom portion of the inflatable pouch to contain the medical equipment therein.

[0019] Additional features, advantages, and embodiments of the invention may be set forth or apparent from consideration of the following detailed description, drawings, and claims. Moreover, it is to be understood that both the foregoing summary of the invention and the following detailed description are exemplary and intended to provide further explanation without limiting the scope of the invention as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] The present invention will be more fully understood from the following detailed description with reference to the accompanying drawings, in which:

[0021] Fig. 1 is a perspective/schematic view of various elements of a kit made in accordance with the principles of the invention;

[0022] Fig. 2 is a perspective view of the primary pouch shown in Fig. 1;

[0023] Fig. 3 is a perspective view of the secondary pouch shown in Fig. 1;

[0024] Figs. 4A and 4B are a front view and cross-sectional view along line IVB-IVB of Fig. 4A, respectively, of the inflatable pouch shown in Fig. 1;

[0025] Fig. 5 is a perspective/schematic view showing an endoscope device and the placement of the protective caps shown in Fig. 1 on the endoscope device;

[0026] Fig. 6 is a perspective view of a medical device equipment hard case that can be used in accordance with the principles of the invention.

[0027] Fig. 7 is a perspective view of a cardboard box that can be used in accordance with the principles of the invention;

[0028] Fig. 8 is a perspective view of a clamshell type embodiment of the inflatable pouch made in accordance with the principles of the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0029] Fig. 1 shows one of the preferred embodiments of the present invention in which a kit 7 can include a primary bag or pouch 1, a secondary bag or pouch 2, an inflatable bag or pouch 3, an inflatable return pouch 3, and a plurality of protective structures such as caps 4. The kit 7 can be provided as a unit to a medical device shipper for use in transporting any variety of medical equipment/devices. Alternatively, the kit 7 can be provided to shippers of various bio-hazardous materials or devices that contain or are contaminated with bio-hazardous materials for safely and efficiently shipping the materials or devices. In addition, the kit 7 can be provided to general shippers who are concerned about shipping other types of dangerous materials. The kit 7 takes up little space since the primary, secondary and inflatable pouches are preferably made of plastic sheets, and the protective caps are also relatively small in size. Accordingly, a hospital, doctor's office, or other shipping location can store many of the kits 7 without requiring a great deal of storage space.

[0030] As shown in Fig. 2, the primary pouch 1 can include a resealable seal 10 located at an open edge or open end 11 of the primary pouch 1. The resealable seal 10 is preferably a

"tongue and groove" type or "zip-lock" seal that has three channels. The three channels securely interlock the opposed plastic sheets at the open end 11 of the primary pouch 1 and prevent fluid leakage. The primary pouch 1 can be made from a plastic material, such as polyethylene, nylon or other material (including woven materials and other water resistant and waterproof materials), depending on the device that the pouch 1 is intended to carry.

[0031] Fig. 3 is a perspective view of the secondary pouch 2 of Fig. 1. The secondary pouch 2 can be similar in construction to the primary pouch 1, but bigger and preferably including an enclosure 22 located on a side of the pouch 2 for placement of shipping documents. The secondary pouch 2 can include a resealable seal 20 located at an open end 21 of the secondary pouch 2. The resealable seal 20 is preferably a "tongue and groove" type or "zip-lock" seal that has three channels. The three channels securely interlock the opposed plastic sheets at the open end 21 of the secondary pouch 2 and prevent fluid leakage. The secondary pouch 2 can be made from a plastic material, such as polyethylene, nylon or other material (including woven materials and other water resistant and waterproof materials), depending on the device that the pouch 2 is intended to carry.

[0032] Fig. 4A shows a front view of the inflatable pouch 3 of Fig. 1. The inflatable pouch 3 preferably includes three heat sealed side edges and a seal 30 located adjacent the fourth side edge which includes open edge or open end 31. The seal 30 preferably allows the inflatable pouch 3 to be closed one time (but if desired, can be resealable), and can include an adhesive strip 326 that runs along a back flap 321 as shown in Fig. 4B. The back flap 321 can extend above a front flap 322 of the open end 31 of the inflatable pouch 3 such that when the back flap 321 is folded over the front flap 322, the adhesive strip 326 can be attached to the front flap 322 to seal the open end 31 of the inflatable pouch 3. Fig 4B shows how heat sealed seams 38 can define baffles 35 in both the front side 310 and rear side 320 of the inflatable pouch 3. The front side 310 of the inflatable pouch 3 can be formed by a front outer side 301 that is heat sealed at seams 38 with a front inner side 311. The heat sealed seams 38 can be configured to define a plurality of baffles 35 in the front side of the inflatable pouch 3.

[0033] The inflatable pouch 3 is preferably sized such that it can be used with common cases provided with new endoscopic equipment. For example, the inflatable pouch can be approximately 23 inches by 24 inches in an uninflated state as viewed from the front, in order to

perfectly fit within standard endoscope cases. The width of the inflatable bag 3 when totally inflated can be approximately 5 inches.

[0034] The front side 310 and rear side 320 form a bladder therebetween that is characterized as a space in which air is trapped. In this particular embodiment, the bladder is segmented in to various portions by a plurality of baffles 35. Baffles 35 can be characterized as portions of the bladder that are recognizable from other different portions of the same bladder. However, the bladder itself can also function as a baffle. Baffles serve to shape the pouch into a specific configuration for use with a particular device or equipment that the pouch is intended to contain, or for use in a particular application.

[0035] As shown in Fig. 4B, the front outer side 301 of the inflatable pouch 3 can be laminated with the front inner side 311 to form the front side 310 of the inflatable pouch 3. Likewise, the back outer side 302 can be laminated with the back inner side 312 to form the back or rear side 320 of the inflatable pouch 3. The laminated portions of the back side of the inflatable pouch 3 form heat sealed seams 38 that also define baffles 35 in the back or rear side of the inflatable pouch 3.

[0036] Side airways 36 can be located at opposite ends of the baffles 35 and/or surrounding the baffles 35 and can be formed by the heat sealed seams 38 such that air can pass between baffles 35 during inflation. The side airways 36 can also function as baffles. Side baffle airways 37 can pneumatically connect baffles 35 with the side airways 36. An air valve 33 is preferably located in one or more of the baffles 35 to provide an entranceway for air into the baffles 35 of the inflatable pouch 3. The air valve 33 can be configured such that a conventional pneumatic air source valve (commonly found in hospitals and medical offices) can be used to inflate the inflatable pouch 3. In addition, the air valve 33 can be configured such that it can be connected to other types of air supplies, such as air pumps, sport needles, and even a manual inflation source. A tear away release valve 39 can be provided in the front outer side 301 of the inflatable pouch 3 so that the air located in the baffles 35 and side airways 36 can be released when desired. The tear away release valve 39 can be configured as an adhesive square placed over a pre-punched hole in the inflatable pouch 3.

[0037] The front outer side 301 and back outer side 302 are preferably made from a nylon/polyethylene laminate, while the front inner side 310 and back inner side 312 are

preferably made from a polyethylene/nylon/polyethylene co-extrusion. However, the materials out of which the inflatable pouch is made can vary in accordance with the particular application, and can be made from a plastic material, such as polyethylene, nylon or other material (including woven materials and other water resistant, waterproof materials, and other materials that can retain air and be inflated). The inflatable pouch 3 can be formed by what is known as a "bag inside a bag" construction. An outer ring of baffles 35 formed by side airways 36 can be provided around the periphery of the inflatable pouch 3 to provide added cushioning and a better fit within a hard case 8 during shipment.

[0038] Fig. 5 shows a perspective view of an endoscope device 5 and protective caps 4. The protective caps 4 are shown adjacent their respective shipping positions on the endoscope device 5. The protective caps 4 are preferably placed over any sharp or protruding surface of the endoscope 5 that could possibly puncture the primary pouch 1, secondary pouch 2, or inflatable pouch 3 during shipment. In particular, protective caps 4 can be provided over a cutter 51 of an endoscope device 5 as well as over adjustment points 52 of the endoscope 5.

[0039] Fig. 6 shows a perspective view of a case 8 that is typically supplied with new medical devices/equipment. The case 8 can include a hard outer case 81 and handle 82. A foam insert is usually located within the case 8 for keeping the medical device in position and for preventing shock or vibration from causing harm to the enclosed medical device/equipment. Most common flexible endoscope equipment cases have an interior volume that has a height of approximately 16 inches, a width of approximately 22.5" inches and thickness or depth of approximately 5 inches when the foam insert is removed. However, other sized cases are sometimes used with new flexible endoscope equipment. For example, the height can vary between approximately 14 and 18 inches, the width can vary between approximately 20 and 24 inches and the depth can vary between approximately 3 and 7 inches and still be considered a typical flexible endoscope equipment case. In fact, even more variations than the above approximate dimensions are possible for typical flexible endoscope equipment cases.

[0040] Fig. 7 is a perspective view of a cardboard box 9 that can be used in place of the case 8 to ship the medical device/equipment or other equipment to be shipped.

[0041] Fig. 8 shows a perspective view of another embodiment of the inflatable pouch of the present invention. In this embodiment, a clamshell style inflatable pouch 6 can be formed such that there is a top portion 61 and a bottom portion 62 connected together by a clamshell folding hinge 64. Baffles 63 can be provided in both the top portion 61 and bottom portion 62. The clamshell style inflatable pouch 6 can be folded along the clamshell folding hinge 64 into a "closed position" to trap or contain an item between the top portion 61 and bottom portion 62. The inflated baffles 63 can prevent the item from moving once the item is sandwiched between the top portion 61 and bottom portion 62.

[0042] An adherence fringe 67 can be located around at least a portion of the periphery of the clamshell style inflatable pouch 6. The adherence fringe 67 can include additional baffles to protect the sides of the enclosed device. The adherence fringe 67 can also include hook and loop strips, adhesive, locks or other attachment devices for securing the respective top and bottom adherence fringes 67 together to secure the clamshell style inflatable pouch 6 in its closed position. When the top portion 61 and bottom portion 62 are folded against and facing each other by folding the clamshell style inflatable pouch 6 at the hinge 64, the adherence fringe 67

along the top portion 61 can be adhered to the opposing portion of the adherence fringe 67 of the bottom portion 62 such the top portion 61 and bottom portion 62 are locked with each other. Thus, the clamshell style inflatable pouch 6 forms a containment area between the top portion 61 and bottom portion 62 to store the medical device/equipment during shipment.

[0043] A flat air valve 65 can be provided in the clamshell style inflatable pouch 6 for connection to a conventional compressed air outlet valve for inflating the baffles 63 of the clamshell style inflatable pouch 6. Airways 69 can be provided to communicate between each of the baffles so that the entire clamshell style inflatable pouch 6 is inflated via the valve 65. A release valve 66 can also be provided on the clamshell style inflatable pouch 6 for releasing the air from within the baffles 63 and airways 69 and facilitating the removal of the device that is enclosed in the clamshell style inflatable pouch 6.

[0044] Preferred embodiments of the method according to the principles of the invention will now be described. According to a preferred embodiment of the invention, a shipper is provided with kit 7. The shipper can take a medical device (such as endoscope 5, for example) that is going to be shipped to another location, and place protective caps 4 on any sharp points or

protruding edges of the endoscope 5. For example, protective caps 4 could be placed over cutter mechanism 51 and side edges 52 of the endoscope 5.

[0045] Once the protective caps 4 are secured to any sharp or protruding areas of the endoscope 5, the endoscope 5 can be placed into the open end 11 of primary pouch 1 and the resealable seal 10 of the inflatable pouch 3 can be sealed to enclose the endoscope 5 within the primary pouch 1. The sealed primary pouch 1 with enclosed endoscope 5 can be placed into secondary pouch 2, and likewise the resealable seal 20 of the secondary pouch 2 can be sealed to enclose the primary pouch 1 and endoscope 5 therein. Any paperwork that is necessary to accompany the shipment can be placed within enclosure 22 located on the outer surface of the secondary pouch 2. The sealed secondary pouch 2 can then be placed in the open end 31 of the inflatable pouch 3. Thus, the inflatable pouch 3 contains the endoscope 5 located in the sealed primary pouch 1 which in turn is located in the sealed secondary pouch 2. The adhesive strip 326 of the inflatable pouch 3 can be exposed and the back flap 321 can be attached by the adhesive strip 326 to the front flap 322 to seal the open end 31 of the inflatable pouch 3.

[0046] Air can be injected via air valve 33 of the inflatable pouch 3 into baffles 35 after the endoscope 5, primary pouch 1 and secondary pouch 2 are placed in the inflatable pouch 3. The inflated baffles 35 and side airways 36 lock the primary pouch 1, secondary pouch 2 and endoscope 5 in place within the inflatable pouch 3.

[0047] Once the endoscope 5 is secured within the inflatable pouch 3 as described above, the sealed inflatable pouch 3 can be placed into a hard case 8 (preferably the original case provided with the endoscope) for shipment to a desired location. The receiver can open the case 8, remove the inflated inflatable pouch 3, and deflate the inflatable pouch 3 via release valve 39 to access the endoscope 5. An additional non-inflated inflatable pouch 3 is preferably included with the shipment of the sealed endoscope 5 so that the receiver can re-package the endoscope 5 for return shipment. Typically, a primary pouch 1 and secondary pouch 2 are not necessary for return shipment because the endoscope is disinfected for before the return shipment.

[0048] Accordingly, after the endoscope 5 is cleaned, repaired, maintained, used, etc., the receiver can repackage the endoscope 5 by placing it into the additional inflatable pouch 3 that was provided with the original shipment. The additional inflatable pouch 3 can be inflated to

secure the endoscope 5 therein, and then placed into case 8 for return shipment to the original sender, or to the next recipient of the endoscope 5.

[0049] In accordance with another preferred embodiment of the invention, a shipper can be provided only with an inflatable pouch 3 and endcaps 4. The endoscope device 5 can be placed directly into the inflatable pouch 3 and secured therein by inflation of baffles 35. The inflated inflatable pouch 3 can then be placed into a shipping container for shipment to a receiver.

[0050] Another preferred embodiment of the invention includes a shipper utilizing a primary pouch 1 to seal an endoscope 5 therein. The sealed endoscope 5 and primary pouch 1 are then placed into the inflatable pouch 3, and the inflatable pouch 3 is inflated, sealed and placed within a shipment container for shipment to a receiver.

[0051] Furthermore, the method can be performed by only performing certain steps of the above described embodiments. For example, the method can include providing an inflatable pouch and a case, and placing the medical equipment/device either into or onto the inflatable pouch. The inflatable pouch can be sealed and placed into the case, and the medical

device/equipment and inflatable pouch can be shipped in the case. No primary pouch or secondary pouch are necessary for use with this particular embodiment of the invention. In addition, this embodiment can include the use of the original case provided with the medical device/equipment. The original case for most endoscopes is typically a hard shell type of case that has a foam insert with cutouts for placement of the endoscope. Without the foam inserts, the dimensions of the inside of the case are approximately 24 inches by 23 inches by 5 inches. In accordance with this embodiment of the invention, the shipper could take the foam inserts out of the original equipment case so that the case can be used with the inflatable pouch. The inflatable pouch can be inflated before the medical device/equipment is placed on the inflatable package, after the inflatable pouch is sealed, or after the inflatable pouch is fit into the case.

[0052] Yet another preferred embodiment of the invention includes using the clamshell style inflatable pouch 6 instead of the inflatable pouch 3 as described in the above preferred embodiments of the invention. When the clamshell style inflatable pouch 6 is used, the shipper places the endoscope 5 either directly onto the clamshell style inflatable pouch 6, or into both the primary pouch 1 and secondary pouch 2 and then onto the clamshell style inflatable pouch 6.

When the endoscope 5 is placed onto the clamshell style pouch 6, the clamshell style pouch is then folded over the endoscope 5 along the hinge 64. The opposing portions of the adherence fringe 67 can then be secured to lock the endoscope between the top portion 61 and bottom portion 62 of the clamshell style inflatable pouch 6.

[0053] The clamshell style inflatable pouch 6 can be inflated at various points during the shipping procedure. For example, the clamshell style inflatable pouch 6 can initially be inflated prior to the endoscope 5 being placed onto the clamshell style inflatable pouch 6. Alternatively, the clamshell style inflatable pouch 6 can be inflated after the adherence fringe portions 67 are adhered to each other to lock the endoscope 5 in place between the top portion 61 and bottom portion 62. The inflation of the clamshell style inflatable pouch 6 can also occur after the endoscope 5 is locked in the clamshell style inflatable pouch 6 and placed into hardshell case 8 or cardboard box 9. In this instance, the inflation can also perfectly secure the clamshell style inflatable pouch 6 within its shipping container.

[0054] Other variations of the above described embodiments of the invention should be considered part of the invention. For example, the method can include inflating the inflatable

pouch 3 or clamshell style inflatable pouch 6 prior to insertion within hardshell case 8, or after insertion within the hardshell case 8. In addition, the shipping container or case can take the form of a hardshell case, cardboard box 9, plastic sleeve or other shipment container.

[0055] With regard to the device that is being shipped, the most common medical equipment or devices that can be shipped in accordance with the invention include all variations of endoscopic devices. Some examples of endoscopic devices that are particularly suited for use with the present invention include the following: gastroscopes; colonoscopies; sigmoidoscopes; duodenoscopes; rhinolaryngoscopes; bronchoscopes; choledochoscoped; intubation scopes; ureteroscopes; ultrasound scopes.

[0056] However the invention is neither limited to the shipment of endoscopic devices nor medical devices in general. Any device that may have a bio-hazardous substance leak or other dangerous material leak would benefit from use in the present invention. For example, bone saws, angioplasty devices, medical laser equipment, etc. could be used in the present invention. In addition, devices for use in treating, sampling or measuring hazardous materials, and devices used to manipulate hazardous material could be used in the present invention.

[0057] The air valve 33 is shown as a flat soft valve, but can be replaced with a hard plastic stem valve, needle valve and other similar air input valve. The inflatable pouch 3 can also be provided with a puncture area that the user can puncture using a sharp or pointy object, such as a golf tee. A hand pump can be used to inflate the inflatable pouch 3, clamshell style inflatable pouch 6, etc. However, it may be more convenient to use an air source structure such as those located in most medical facilities for inflation of the device. The release valves 39 and 66 can be formed as a tape-like seal located over a prepunched hole in the inflatable pouch 3 or clamshell style inflatable pouch 6, respectively. However, other deflation mechanisms can also be used, such as a hard plastic stem valve with cap, a rippable portion of the inflatable pouch or baffle, etc.

[0058] The protective structure is shown as a cap 4. However, it is conceivable that other protective structures can be used in the invention, such as tape or a gel type substance placed over protruding or sharp edges of the device to be shipped. In addition, a foam sleeve or pouch, or bubble wrap can be used to protect portions of the medical device/equipment. The caps and other protective structures are preferably made of plastic, rubber or other polymers, but can be

made of other materials provided that they can protect the device or equipment being shipped and protect the pouches in which the device or equipment is shipped.

[0059] The baffles 35 and 63 can be formed by heat sealing the inner and outer plastic sheets that make up the front and back sides of the inflatable pouch 3 and clamshell style inflatable pouch 6, respectively. However, other structures can be used to form the baffles 35 and 63, such as laser welds, sewed seams, adhesive bonds, etc. In addition, the shape of the baffles can vary in accordance with the device that is to be carried. For example, the baffles 35 are shown as elongate shapes with rounded ends. However, the baffles could be shaped as triangular, can be non-symmetrical, and can be any other shape that would help constrain the device that is to be contained and/or used in the present invention. In addition, the baffles on the front side do not necessarily have to be the same shape, size or number as the baffles on the back or rear side of the inflatable pouch. Preferably, the baffles are shaped such that when the inflatable pouch 3 is inflated, it conforms to the shape of the interior of a standard medical device case, such as an endoscope case.

[0060] The manner in which air is dispersed between the baffles can also change without departing from the spirit or scope of the present invention. As shown in Figs. 4A, 4B and 8, air can be dispersed via baffle airways 37 formed as slits in the baffles 35 themselves, or through airways 69 formed as tubes connected between each of the baffles 63. In addition, air can be dispersed via different structures, such as additional interconnected baffles, separate tubes or ducts extending out of and between the baffles, or other structures. In addition, the number, size and distribution of airways can be varied to control the distribution and timing of air entering and filling the baffles such that distribution and timing can occur in a predetermined way. Likewise, certain baffles can be interconnected via a first system of interconnected airways, while other baffles are connected to a different system of separately interconnected airways. Thus, different baffles can be inflated/deflated at different times.

[0061] The timing at which inflation of the inflatable pouch 3, clamshell style inflatable pouch 6, or other pouch occurs can also vary while remaining within the scope of the invention. In addition, the timing at which the device is placed within the primary pouch, within the secondary pouch and within the inflatable pouch can also vary. For example, the pouch can be

inflated after it is placed within a case, or prior to placement in the case. In addition, the pouch can be inflated prior to or after the times at which the device/equipment that is to be shipped is placed in the primary pouch, secondary pouch or inflatable pouch. Different advantages are associated with the various timings for inflation and placement.

[0062] For example, inflation of the inflatable pouch after it is placed within the case allows a tight fit within the case. On the other hand, inflation of the pouch immediately after the device to be shipped is placed into the pouch provides certainty and exactness in stabilizing and protecting the device in the inflatable pouch. Similarly, inflation of the inflatable pouch prior to when any of the primary pouch, secondary pouch or device to be shipped are placed in the inflatable pouch permits the shipper to orient the primary pouch, secondary pouch or device to be shipped such that it is optimally aligned in the inflated inflatable pouch for securing the device (and primary and secondary pouches) during shipping.

[0063] The basic configuration of the inflatable pouch 3 and clamshell style pouch 6 can also vary. For example, the overall shape of the pouch can be rectangular, square, triangular, oval or other shape, depending on the size and configuration of the device that is to be shipped or

the particular application. In addition, there can be three-dimensional changes in the configuration of the pouch, such as the addition of protrusions and extensions from and recesses in the base geometrical configuration so that the pouch comports with the device to be shipped.

[0064] Shipping of a device or equipment can include mailing the device or equipment through standard mail services, and can also include placing the device or equipment with a common courier for shipment. In addition, shipping can include the use of intra-office delivery services for transporting the device or equipment from one location to another. Shipping can also include the use of various other courier services, such as bicycle couriers, taxi couriers, street couriers, etc.

[0065] In addition, the inventive method can be accomplished using only the primary pouch or only the secondary pouch with the remaining steps of the method without departing from the scope of the invention. The primary and secondary pouches are preferably waterproof. Accordingly, the seal at their respective open ends are preferably waterproof, and can include the channels (as described above) and can also include permanent waterproof adhesive strips, nylon waterproof zipper structures, heat sealable areas, etc.

[0066] Having described the preferred embodiments consistent with the invention, other embodiments and variations consistent with the invention will be apparent to those skilled in the art. Therefore, the invention should not be viewed as limited to the above disclosed embodiments but rather should be viewed as limited only by the spirit and scope of the appended claims.